

SETTLEMENT AGREEMENT

I PARTIES

This Settlement Agreement ("Agreement") is entered into by the State of Michigan and Otsuka America Pharmaceutical, Inc ("Otsuka"), through their authorized representatives (hereinafter referred to as "the Parties")

II PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A WHEREAS, at all relevant times, Otsuka, a Delaware corporation headquartered in Rockville, Maryland, marketed and sold pharmaceutical products in the United States;

B. WHEREAS, on or about February 3, 2005, Joseph Piacentile filed a *qui tam* action in the United States District Court for the District of Massachusetts captioned United States ex rel. Piacentile v. Bristol-Myers Squibb Co., Civil Action No 05-10196-MLW (D Mass) (the "Piacentile Action");

C. WHEREAS, Otsuka has entered into a separate settlement agreement (hereinafter referred to as the "Federal Settlement Agreement and Release") with the United States Department of Justice (hereinafter referred to as the "United States") which has received settlement funds from Otsuka pursuant to Paragraph III 1 A below for the Covered Conduct described in Paragraph II E below;

D WHEREAS, the State of Michigan alleges that Otsuka caused to be submitted claims for payment for its drugs to the State of Michigan's Medicaid Program,

established pursuant to the Title XIX of the Social Security Act, 42 U S C Sections 1396-1396v;

E WHEREAS, the State of Michigan contends that it has certain administrative and civil claims against Otsuka for allegedly engaging in the following conduct (hereinafter the "Covered Conduct"):

The State of Michigan contends that, during the period from January 2002 through December 2005, Otsuka knowingly promoted the sale and use of Abilify (aripiprazole) for pediatric use (i.e., for patients younger than 18) prior to approval for these uses by the United States Food and Drug Administration ("FDA") and to treat dementia-related psychosis, a use for which FDA has not approved Abilify. The State of Michigan contends that Otsuka's promotion of Abilify for these unapproved uses violated the Food, Drug and Cosmetic Act ("FDCA"), 21 U S C Sections 331(a) & (d). Furthermore, the State of Michigan contends that, during the relevant time period, these uses were not medically-accepted indications, as defined by 42 U S C Section 1396r-8(k)(6) (uses approved under the FDCA or included in or approved for inclusion in specified drug compendia), and that certain State Medicaid Programs did not cover Abilify dispensed for these uses.

F WHEREAS, this Agreement is neither an admission of facts or liability by Otsuka nor a concession by the State of Michigan that its claims are not well founded;

G WHEREAS, to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach full and fair settlement as set forth below

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations set forth below in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1 Otsuka agrees to pay, or has paid, the United States and the States that will be receiving settlement funds pursuant to this paragraph (the "Medicaid Participating States"), collectively, the sum of three million, nine hundred thousand dollars (\$3,900,000), plus interest in the amount of 4.625% per annum from March 1, 2007, and continuing until and including the day before complete payment is made (the "Settlement Amount") The portion of this sum designated, as provided in this Agreement, for the Medicaid Participating States, shall constitute a debt immediately due and owing to the Medicaid Participating States on the Effective Date of this Agreement, subject to the terms of this Agreement and the Federal Settlement Agreement and Release This debt is to be discharged by payments to the Medicaid Participating States, under the following conditions:

A Otsuka has paid to the United States the sum of two million, two hundred sixty-two thousand, one hundred seventy-four dollars (\$2,262,174), plus interest in the amount of 4.625% per annum (\$286.65 per day) from March 1, 2007, and continuing until and including the day before complete payment was made (the "Federal Settlement Amount") This Federal Settlement Amount represents a payment of two million, one thousand, seven hundred fifty-two dollars (\$2,001,752) to the Medicaid

Program, and a payment of two hundred sixty thousand, four hundred twenty-two dollars (\$260,422) to the Department of Defense, the Veterans' Administration, and the Federal Employee Health Benefit Program. The Federal Settlement Amount was paid by electronic funds transfer pursuant to written instructions provided by the United States

B Otsuka shall pay to the Medicaid Participating States the sum of one million, six hundred thirty-seven thousand, eight hundred twenty-six dollars (\$1,637,826), plus interest accrued thereon at the rate of 4.625% per annum (\$207.53 per day) from March 1, 2007, continuing until and including the day before complete payment is made (the "Medicaid State Settlement Amount"). It is understood and agreed by the parties that, to the extent that some States decide not to participate in the settlement of this matter, the total amount due and owing to the Medicaid Participating States shall be reduced proportionately to reflect the lack of participation of those states. This Medicaid State Settlement Amount shall be paid no later than seven business days after Otsuka receives written payment instructions from the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team for the Medicaid Participating States and following the earliest of the dates on which the following occurs: (1) the Medicaid State Settlement Agreements are fully executed by Otsuka and the Medicaid Participating States and delivered to Otsuka's attorneys, or (2) as otherwise agreed in writing by Otsuka and the NAMFCU Negotiating Team.

C The total portion of the Settlement Amount paid by Otsuka in settlement for the Covered Conduct to the State of Michigan is \$129,842.96 consisting of a portion paid to the State of Michigan under this agreement and another portion paid to the federal government as part of the Federal Settlement Agreement and Release. The

individual portion of the Medicaid State Settlement Amount allocable to the State of Michigan under this agreement is \$57,652 04, plus applicable interest (the "Individual State Settlement Amount"):

2. Contingent upon the Medicaid Participating States receiving the Medicaid State Settlement Amount, the Medicaid Participating States agree to pay, as soon as feasible after receipt, an agreed upon amount to relator Piacentile that has been addressed via a side letter with relator and his attorney

3. Subject to the exceptions in Paragraphs 5 below, and in consideration of the obligations of Otsuka set forth in this Agreement, conditioned upon Otsuka's payment in full of the Settlement Amount, and subject to Paragraph 12 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), the State of Michigan, on behalf of itself, and its officers, agents, agencies, political subdivisions and departments, agrees to release Otsuka, its predecessors, divisions, subsidiaries, parents, sister affiliates, successors and assigns, and its current and former directors, officers, and employees, from any civil or administrative monetary claim that the State or any of its political subdivisions has or may have for any claims submitted or caused to be submitted to its Medicaid Program for the Covered Conduct. For purposes of this Agreement, "sister affiliates" means Otsuka Pharmaceutical Development and Commercialization, Inc and Otsuka Maryland Medicinal Laboratories, Inc

4. Notwithstanding any term of this Agreement, the State of Michigan specifically does not release any person or entity from any of the following claims or liabilities: (a) any criminal, civil, or administrative claims arising under its revenue

codes; (b) any criminal liability not specifically released by this Agreement; (c) any civil or administrative liability that Otsuka has or may have under any state statute, regulation, or rule not covered by this release; (d) any liability to the State of Michigan (or any agencies thereof) for any conduct other than the Covered Conduct; (e) any claims based upon obligations created by this Agreement; (f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from the State of Michigan's Medicaid Program; (g) any express or implied warranty claims or other claims for defective or deficient products and services provided by Otsuka; (h) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (i) any claim based on a failure to deliver items or services due.

5. In consideration of the obligations of Otsuka set forth in this Agreement, and the Corporate Integrity Agreement that Otsuka has entered into with the Office of the Inspector General, United States Department of Health and Human Services ("HHS-OIG") in connection with this matter (the "CIA"), conditioned on Otsuka's payment in full of the Settlement Amount, except as reserved in Paragraph 4 above and subject to Paragraph 12 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), the State of Michigan agrees to release and refrain from instituting, directing, or maintaining any administrative claim or any action seeking exclusion from its Medicaid Program against Otsuka or its predecessors, divisions, parents, subsidiaries, sister affiliates, successors, and assigns for the Covered Conduct. Nothing in this Agreement precludes the State of Michigan from taking action against Otsuka in the event that Otsuka is excluded by the

federal government, or for conduct and practices other than the Covered Conduct. The State of Michigan does not release Otsuka from any claims or actions which may be asserted by private payors or insurers, including those that are paid by a state's Medicaid Program on a capitated basis.

6. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

7. The State of Michigan agrees to dismiss with prejudice any lawsuit specifically as to Otsuka, including any *qui tam* "whistleblower" lawsuit, in which the state has intervened and/or has the authority to dismiss, currently pending against Otsuka in the courts of the State of Michigan for the Covered Conduct as defined in Paragraph E of this Agreement, and declines to intervene in other claims asserted against Otsuka in the Piacentile Action. Otsuka waives and shall not assert any defense it may have to criminal prosecution or administrative action relating to the Covered Conduct, which defense may be based in whole or in part on a contention that, under the Double Jeopardy Clause of the Fifth Amendment of the Constitution or the Excessive Fines Clause of the Eighth Amendment of the Constitution, this agreement bars a remedy sought in such criminal prosecution or administrative action.

8. In consideration of the obligations of the State of Michigan set forth in this Agreement, Otsuka, on behalf of itself and its predecessors, divisions, parents, subsidiaries, sister affiliates, successors and assigns, fully and finally releases and discharges the State of Michigan, its agencies, political subdivisions, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which Otsuka has asserted, could have asserted, or

could assert in the future against the State of Michigan, its agencies, political subdivisions, employees, servants, and agents, related to or arising from the State's investigation and prosecution of the Covered Conduct

9 The Settlement Amount that Otsuka must pay pursuant to Paragraph 1 above will not be decreased as a result of the denial of claims for payment now being withheld from payment by the State's Medicaid Program or any other state payer, related to the Covered Conduct, and Otsuka agrees not to resubmit to the State's Medicaid Program or any other state payer, any previously denied claims, which denials were based on the Covered Conduct, and agrees not to appeal or cause the appeal of any such denials of claims

10 Otsuka agrees that it shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers. Otsuka waives any causes of action against these beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims for payment covered by this Agreement.

11 Otsuka expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Otsuka within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange

12 In the event Otsuka commences, or another party commences, within 91 days of the Effective Date of this Agreement or any payment made hereunder, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Otsuka's debts, or seeking to adjudicate Otsuka as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for Otsuka, or for all or any substantial part of Otsuka's assets, Otsuka agrees as follows:

A Otsuka's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Otsuka shall not argue or otherwise take the position in any such case, proceeding or action that: (i) Otsuka's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Otsuka was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States and the Medicaid Participating States pursuant to paragraph III 1 of this agreement; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Otsuka

B If Otsuka's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the State of Michigan, at its sole option, may rescind the releases provided in this Agreement, and bring any civil and/or administrative claim, action or proceeding against Otsuka for the claims that would otherwise be covered by the releases provided in this Agreement. If the State of Michigan chooses to do so, Otsuka agrees that for purposes only of any

claims, actions or proceedings referenced in the first sentence of this Paragraph, (i) any such claims, actions, or proceedings brought (including any proceedings to exclude Otsuka from participation in the State of Michigan's Medicaid Program) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a), as a result of the action, case, or proceeding described in the first sentence of this Paragraph, and that Otsuka shall not argue or otherwise contend that such claims, actions, or proceedings are subject to an automatic stay; (ii) Otsuka shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings which are brought by the State of Michigan within 90 calendar days of written notification to Otsuka that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before January 24, 2007; and (iii) the United States and the Participating States have a valid claim against Otsuka in the amount of three million, nine hundred thousand dollars (\$3,900,000.00) plus applicable multipliers and penalties and they may pursue their claims, *inter alia*, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action or proceeding; and

C Otsuka acknowledges that its obligations in this Paragraph are provided in exchange for valuable consideration provided in this Agreement

13. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity

14. Nothing in this Agreement constitutes an agreement by the State of Michigan concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code

15 In addition to all other payments and responsibilities under this Agreement, Otsuka agrees to pay all reasonable travel costs and expenses of the NAMFCU Negotiating Team Otsuka will pay this amount by separate check or wire transfer made payable to the National Association of Medicaid Fraud Control Units, after the respective Medicaid Participating States execute this agreement or as otherwise agreed by the parties

16 This agreement does not constitute an admission by any person or entity, and shall not be construed as an admission by any party or entity, with respect to any issue of law or fact

17 This Agreement is governed by the laws of the State of Michigan

18 The undersigned Otsuka signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement The undersigned State of Michigan signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the State of Michigan through their respective agencies and departments

19 The "Effective Date" of this Agreement shall be on the date of signature of the last signatory of Otsuka or of the Medicaid Participating State to the Agreement Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement

20. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties


21. This Agreement shall not be amended except by written consent of the Parties.

THE STATE OF MICHIGAN

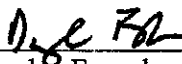
By: Elizabeth Valentine Dated: 10/27/09
Name Elizabeth Valentine
Title Assistant Attorney General, Health Care Fraud Division
Office of the Attorney General

By: James R Brandell Dated: 10/26/2009
Name
Title Director, Medicaid Financial Mgmt &
Medicaid Program Administrative Services

OTSUKA AMERICA PHARMACEUTICAL, INC.

By: 
Mark Altmeyer
Title: Chairman & CEO
Otsuka America Pharmaceutical, Inc.

Dated: 11/12/09

By: 
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Dated: 11/10/09